

COMMENT:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

	TOXIC SUBSTANCES
	February 19, 2009
DP BARCODE:	D360604
MRID:	476277-00, 476277-01
SUBJECT:	UCARCIDE™ 14 Antimicrobial
REG. NO. OR FILE SYMBOL:	464-700
DOCUMENT TYPE:	Product Chemistry Review
Manufacturing-use [] OR	End-use Product [X]
INGREDIENTS (PC Codes)	Glutaraldehyde (043901), n-Alkyl (50% C_{14} , 40% C_{12} , 10% C_{16}) dimethyl benzyl ammonium chloride (069105)
CAS Number:	(111-30-8), (68424-85-1)
TEST LAB:	
SUBMITTER:	The Dow Chemical Company
GUIDELINE:	830.1800 Enforcement Analytical Method
COMMODITIES:	Formulation
REVIEWER:	Juan F. Negrón
ORGANIZATION:	AD
APPROVER:	Karen P. Hicks
APPROVED DATE:	02/19/09



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February 19, 2009

MEMORANDUM Subject: Product Chemistry Review for EPA Reg # 464-700. From: Juan F. Negrón, Chemist Product Science Branch, CT Team Antimicrobials Division (7510P) Thru: Karen P. Hicks, CT Team Leader Product Science Branch Antimicrobials Division (7510P) Thru: Michele E. Wingfield, Chief **Product Science Branch** Antimicrobials Division (7510P) To: Marshall Swindell / Martha Terry PM Team 33 **APPLICANT:** The Dow Chemical Company **Action code:** 362 **Due date:** 03/03/09 **Product Formulation Active Ingredient(s)** % by wt.

	, v 23
Glutaraldehyde	14.0
n-Alkyl (50%C ₁₄ , 40% C ₁₂ , 10% C ₁₆)	
dimethyl benzyl ammonium chloride	2.5

BACKGROUND:

The registrant, The Dow Chemical Company, has submitted an amendment application for the non-integrated end-use product, UCARCIDETM 14 Antimicrobial. The registrant is updating the enforcement analytical method. The Product Chemistry Reviewer has received the following documents:

- A letter, dated 11/25/08. MRID # 476277-00.
- A label, dated 04/04/08.
- Application for pesticide amendment, dated 11/25/08.
- Certification with respect to citation of data, dated 11/25/08.
- Data matrix, dated 11/24/08.
- A study titled "Glutaraldehyde concentration by Ppotentiometric Hydroxylamine Hydrochloride Titration." MRID #476277-01.

FINDINGS:

- 1. No CSF was submitted.
- 2. The registrant submitted an update enforcement analytical method for eleven products which are; 464-700, 464-693, 464-688, 464-702, 464-692, 464-704, 464-690, 464-691, 464-689, 464-696, and 464-707. Registrant provided extra copies that contains letter, application for pesticide amendment, certification with respect to citation of data, and data matrix for the other EPA Registrations mentioned above.
- 3. The registrant updated the analytical method to cover a wider range of active ingredient (AI) concentration to be from 1% to 50% of glutaraldehyde.
- 4. On page 9 of 11, the AI concentration has been tested from 12.8% to 50%.
- 5. On page 11 of 11, the linearity indicates that the titrator response was found to be linear over the nominal concentration range of 15 to 50% (wt/wt) glutaraldehyde in water.

RECOMMENDATIONS:

- 1. The product needs to be tested for 1% instead of 12.8% as the lower range.
- 2. The linearity range must be below 1% as the lower range and not 15%.

CONCLUSIONS:

The enforcement analytical method is not acceptable. The proposed amendment is not acceptable. The method does not cover the range that the registrant proposed.